I. PURPOSE

This procedure provides instructions for performing fecal occult blood testing using Beckman Coulter Hemoccult® slides and Developer. The Hemoccult® test is a rapid, qualitative method for detecting fecal occult blood.

II. ORDER

A physician’s order, standard protocol, or order by another health professional authorized to request laboratory tests is required for point of care fecal occult blood testing.
III. MATERIALS

<table>
<thead>
<tr>
<th>Reagents</th>
<th>Source</th>
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<tbody>
<tr>
<td>Hemoccult® Slides</td>
<td>SAP Item #3717</td>
</tr>
<tr>
<td>Hemoccult® Developer</td>
<td>SAP Item #4489</td>
</tr>
</tbody>
</table>

**Additional Supplies**

- Disposable Gloves
- JHMI Quality Control Labels: Standard Register Item #0209N
- Applicators: Comes in each Slide Box
- JHMI-approved Biohazard Waste Container
- NIST-Certified Timing Device

IV. STORAGE AND HANDLING REQUIREMENTS

<table>
<thead>
<tr>
<th></th>
<th>Temperature</th>
<th>Expiration Date</th>
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<tbody>
<tr>
<td>Hemoccult® Slides</td>
<td>Room Temperature (15-30°C)</td>
<td>Manufacturer's expiration date.</td>
</tr>
<tr>
<td>Hemoccult® Developer</td>
<td>Room Temperature (15-30°C)</td>
<td>Manufacturer's expiration date.</td>
</tr>
</tbody>
</table>

A. Once a box of Hemoccult® Slides or a bottle of Hemoccult® Developer is opened, it is required that the consumable is labeled with the open date.

B. Never use Hemoccult® Slides or Developer past the manufacturer’s expiration date.

C. Do not freeze or refrigerate the Hemoccult® Slides or Developer.

D. Hemoccult® Slides must remain in their original packaging, protected from heat and light.

E. Hemoccult® Developer must remain tightly capped when not in use to prevent evaporation.

   1. Due to flammability, do not store near volatile chemicals.

V. SPECIMEN TYPE

The preferred sample for testing is fecal samples, either a single sample or three consecutive bowel movements on separate Hemoccult® Cards. As bleeding from gastrointestinal lesions may be intermittent, it is recommended that fecal samples for testing be collected from three consecutive bowel movements or three bowel movements closely spaced in time.

VI. SPECIMEN COLLECTION AND HANDLING

Prior to sample collection, patient identification must be verified using two unique identifiers.

A. Clean collection containers must be labeled with at least two unique patient identifiers in front of the patient (e.g. Name, DOB, MRN, and/or CSN).

B. All labeling should be done on the cup instead of the lid as applicable, which may become separated from the specimen.

Whenever possible, the patient should be placed on the Special Diagnostic Diet at least 72 hours before and continuing through the test period. This diet can increase the accuracy of the test results and may provide roughage to help uncover “silent lesions” that bleed intermittently.
Subject
Fecal Occult Blood - Hemoccult

A. Foods to Eat:
1. Well-cooked pork, poultry, and fish.
2. Any cooked fruits and vegetables.
3. High fiber foods.
4. Moderate amounts of raw fruits and vegetables, other than those listed below.
5. Moderate amounts of alcoholic beverages

B. Foods, Drugs and Vitamins to Avoid:
1. Red meat, including processed meats and liver.
2. Any melons, radishes, turnips, and horseradish.
3. Vitamin C in excess of 250 mg/day.
4. Aspirin and other non-steroidal anti-inflammatory drugs (avoid for 7 days prior to and during the testing period).

VII. SAFETY PRECAUTIONS
A. Follow ICPM IFC023 Infection Control and Prevention: Standard and Isolation Precautions.
B. The Hemoccult® Developer is an irritant; avoid unnecessary exposure and wash area of contact with water immediately.
C. All patient specimens, Hemoccult® Slides, and applicators must be discarded in the appropriate JHMI-approved biohazard container or waste receptacle.

VIII. PERFORMING QUALITY CONTROL (QC) TESTS
A. Internal Performance Monitors:
1. Each Hemoccult® Slide contains two Performance Monitors to test the function and stability of the Hemoccult® consumables. Both results must be acceptable for results of any kind to be reported.
2. Negative Performance Monitor:
   a. Upon application of the Hemoccult® Developer, this area on the Hemoccult® slide will not develop any color.
3. Positive Performance Monitor:
   a. Upon application of the Hemoccult® Developer, this area on the Hemoccult® slide will turn blue within 10 seconds and remain stable for at least 60 seconds.
4. If either of these performance monitors fails to react as expected, the test is reported as Invalid and must be repeated using a new bottle of Hemoccult® Developer and/or a new box of Hemoccult® Slides. Refer to Corrective Action below.
B. Internal Performance Monitors will be assessed:
1. After every patient test performed.
2. At least once weekly as a part of weekly QC on each opened box of Hemoccult® Slides and each opened bottle of Hemoccult® Developer.
3. Initially when opening new Hemoccult® Slides or Hemoccult® Developer.
4. By all new operators as part of initial hands-on training prior to testing patient specimens.
5. At least once a year by each operator to demonstrate compliance with competency regulations.
C. Procedure:
1. Prepare materials for testing:
   a. Put on gloves.
   b. Verify that the Hemoccult® Slides and Hemoccult® Developer are dated and within the manufacturer's expiration date.
      i. If a new box of Hemoccult® Slides or bottle of Hemoccult® Developer has been opened, label with the open date, at minimum.
   c. Remove one Hemoccult® Slide from the box and label appropriately to indicate weekly QC.
   d. Set timer to 10 seconds.

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Subject  
Fecal Occult Blood - Hemoccult

i. Note: Use of a wall clock or wristwatch to time the test is insufficient; a NIST-certified timer must be used.

2. Perform the test:
   a. Record the applicable information onto the Hemoccult QC Log Sheet (Appendix A).
   b. Mix the Hemoccult® Developer gently by inversion, then open the smaller flap on the back of the slide.
   c. Apply 1 drop of Hemoccult® Developer between the positive and negative Performance Monitor areas, then press Start on the timer.
   d. Interpret the results within 10 seconds.
      i. If the Hemoccult® Slides and Developer are functional, a blue color will appear in the positive
         Performance Monitor area, and the negative Performance Monitor area will remain the same paper color.
   e. Record the results as Pos/Positive or Neg/Negative on the Hemoccult QC Log Sheet in the appropriate boxes, and place a check mark in the QC Pass/Fail column to indicate whether QC was successful.
      i. Note: Do not use (+) or (-) signs.
   f. Dispose of the used Hemoccult® Slide in the appropriate waste receptacle.

D. Corrective Action:
   1. If either Performance Monitor fails to give the expected results:
      a. Verify the Hemoccult® Slides and Hemoccult® Developer are within their expiration dates and have been properly stored.
      b. Ensure proper testing technique is being used, repeating testing with the same materials.
      c. If QC fails a second time, replace the Hemoccult® Developer with a new bottle and repeat QC testing.
      d. If QC fails a third time, replace the Hemoccult® Slides with an unopened box and repeat testing.
      e. If QC fails with the new Hemoccult® Developer and Hemoccult® Slides, DO NOT PERFORM ANY
         PATIENT TESTING. Contact the POCT Office (5-2645) or by sending a CORUS Message to "POCT
         Consult".
   2. Note any QC failures and corrective actions in the Comment Section of the Hemoccult QC Log Sheet.

IX. PATIENT TEST PROCEDURE

A. Prepare for the test:
   1. Confirm the Hemoccult® Slides and Hemoccult® Developer are not expired and that QC testing has been performed successfully and documented within the last week. If not, QC must be completed prior to patient testing. Refer to Performing Quality Control (QC) Tests.
   2. Put on gloves.
   3. Confirm proper specimen labeling, with at least two unique identifiers on the cup, not the lid, as applicable.
   4. Remove a slide from the box and record at least two patient identifiers on the front slide flap in the space provided.
      a. Note: This can be accomplished by writing the identifiers, or by placing a patient label in the indicated area on
         the Hemoccult® Slide.
   5. Set timer for a minimum of 3 minutes.
      1. Note: Use of a wall clock or wristwatch to time the test is insufficient; a NIST-certified timer must be used.

B. Apply the patient sample:
   1. Open the slide on the slide indicated for application so that the two application areas (Box A and Box B) are visible.
   2. Collect a small fecal sample on one end of an applicator stick.
   3. Apply a thin smear inside Box A.
   4. Use the opposite end of the applicator stick to obtain a second sample from a different part of the fecal sample.
   5. Apply a thin sample inside Box B.
   6. Close the cover of the slide and turn over.
   7. Press Start on the timer.
   8. Wait at least 3-5 minutes to ensure drying of the specimen before continuing with patient testing.
9. Discard the used applicator stick in a hard-sided Sharps container.

C. Perform the patient test:
1. Set the timer for 1 minute.
2. Open the flap on the back of the slide and apply 2 drops of Hemoccult® Developer to the guaiac paper directly over each smear.
3. Press Start on the timer.
4. Within 60 seconds, read the fecal occult blood results. Development of any trace blue color is regarded as a positive result.
5. Add one drop of Hemoccult® Developer between the positive and negative Performance Monitor areas.
6. Interpret results within 10 seconds.
7. If the Hemoccult® Slide and Developer are functional, a blue color will appear in the positive Performance Monitor area and the negative Performance Monitor area will remain unchanged.
8. If a computer is not in the same room as that in which patient testing is performed, complete the Hemoccult Patient Result Log (see Appendix B). If a computer is available in the same room as testing, immediately result the test in the patient's electronic medical record.
9. Discard the patient specimen and Hemoccult® Slide in the appropriate JHMI-approved biohazard container or waste receptacle.

X. EXPECTED RESULTS
Results are expected to be negative; however, positivity rates for fecal occult blood tests vary in each patient population depending on diet, age, predisposition to colorectal disease and other factors. In a general screening population of asymptomatic individuals, the Hemoccult® test will yield a positivity rate of approximately 2-5%, with a false positive rate of approximately 1-2%.

XI. RESULTS INTERPRETATION
A. Positive: Presence of additional blue color over the sample in the occult blood test area after the addition of the Hemoccult® Developer, given the appropriate Performance Monitors reactions.
   1. Some specimens have a high bile content which may cause the feces to appear green. A blue or blue-green color should be interpreted as positive for fecal occult blood.
B. Negative: Absence of additional blue color over the sample in the occult blood test area after the addition of the Hemoccult® Developer, given the appropriate Performance Monitors reactions.
   1. Some specimens have a high bile content which may cause the feces to appear green. A distinct green color with no blue appearing on or at the edge of the smear within 60 seconds after adding the developer should be interpreted as negative for fecal occult blood.
C. Invalid: If the positive Performance Monitor and/or negative Performance Monitor does not react as expected, no patient results can be reported until the failures are corrected.

Note: All test results should be considered in relation to a specific patients' condition and therapy; questionable results or results that do not match the clinical condition should be reported to the patient's provider to determine if additional follow-up is needed. If clinically indicated, patients on unrestricted diets that test positive on one or more of the initial 3 slides may be placed on the Special Diagnostic Diet and then retested for three bowel movements.

XII. RESULTS REPORTING
All patient results must be manually documented on the Hemoccult Patient Result Log (see Appendix B) if there is not a computer in the room where testing is performed. The log must then be used to ensure results are properly documented in Epic using Manual Entry. If there is a computer in the testing room, patient result entry must occur immediately following the completion of testing.

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A. Each of the fields must be filled out completely when completing the Hemoccult Patient Result Log.
   1. Record the patient's fecal occult blood test result as “Pos” or “Positive” for a positive result, or “Neg” or “Negative” for a negative result.
      a. Note: Do not use (+) or (-) symbols for recording fecal occult blood test results.
   2. See Epic Tips and Tricks on how to Enter/Edit Results.

In the event of an Epic downtime, all patient results must be recorded on the Hemoccult Patient Result Log until the downtime is over, at which time all patient results must be manually entered in Epic.

XIII. INTERFERENCES
Refer to the package insert for a full list of Interfering Substances for the Hemoccult® test. Positive and negative interferences should be kept in mind when interpreting results of the Hemoccult® test.

A. Foods, drugs, vitamins or other substances that can cause false-positive or false-negative tests for at least 72 hours before and continuing through the test period.
B. Aspirin and other non-steroidal anti-inflammatory drugs should be avoided for at least 7 days prior to and continuing through the test period.
C. Application of antiseptic preparations containing iodine to the anal area can cause a false-positive result.
D. Samples taken during a rectal examination may give misleading, positive results. Minimal occult rectal trauma could cause a positive result.

XIV. LIMITATIONS
A. The Hemoccult® test is designed for preliminary screening as an aid to diagnosis, and is not intended to replace other diagnostic procedures.
B. Blood, even if present, may not be distributed uniformly in fecal specimen. As such, a test result may be negative even when disease is present.
   1. The test may be positive due to low but detectable levels of blood loss, common in both healthy adults and in patients with gastrointestinal disease.
   2. Bowel lesions, including colorectal cancers, may not bleed at all or may bleed intermittently.
   3. The test may be positive for samples from healthy patients due to interfering substances in the diet or medications.
C. Fecal samples should not be collected if hematuria or obvious rectal bleeding, such as from hemorrhoids, is present.
D. Menstruating women must be instructed to avoid collecting fecal samples during or in the first three days after a menstrual period.
E. The Hemoccult® Test is not recommended for use with gastric samples.
F. Results with the Hemoccult® test cannot be considered conclusive evidence of the presence or absence of gastrointestinal bleeding or pathology.

XV. PROCEDURAL NOTES
A. Some specimens have a high bile content which may cause the feces to appear green; take care when interpreting the smear after addition of the Hemoccult® Developer for color change.
B. Interferences should be kept in mind when interpreting the results of the Hemoccult® test.

XVI. OPERATOR TRAINING
A. Testing may only be performed by currently certified staff members who have been trained by a Point of Care Coordinator, Nurse Educator, or designated unit trainer. Training records must be kept in the employee's personnel file, and a copy sent to the Point of Care Testing Office.
B. Initial Training will include:
1. Review the policy online.
2. Completion of the Initial Training and Competency Assessment Checklist (see Appendix C), to be kept in the employee's personnel file.
3. Successful performance and documentation of quality control (e.g. the Performance Monitors).
4. Passing score on the quiz from the MyLearning module.

XVII. OPERATOR COMPETENCY
In order to maintain competency, operators must successfully complete and document quality control (Performance Monitors) and the MyLearning module and quiz once a year. The competency calendar follows the fiscal year: July 1-June 30.

XVIII. REFERENCES

XIX. SIGNATURES

<table>
<thead>
<tr>
<th>Electronic Signature(s)</th>
<th>Date</th>
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<tr>
<td>William Clarke</td>
<td>11/09/2023</td>
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<tr>
<td>Medical Director of Point of Care Testing</td>
<td></td>
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<tr>
<td>Andrew Satin</td>
<td>11/09/2023</td>
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<td>CLIA Laboratory Director</td>
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<td>Tsion Abdi</td>
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<tr>
<td>Alyssa Parian</td>
<td>11/08/2023</td>
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